

closures during handling of the catheterization device, leakage of the wetting liquid is prevented, and the sheath lumen and the urine collection vessel are not in fluid communication. The embodiment of FIG. 2C or FIG. 6 may be preferred for ease of manufacture and for cost considerations.

[0068] An amount of wetting liquid, preferably water or saline, that is sufficient to thoroughly wet the catheter is placed in the sheath prior to sealing. Alternatively, a similar amount of wetting liquid is placed inside second guide section 220 (FIGS. 6 and 7B). As mentioned above, in this configuration the wetting liquid does not leak through the unopened diaphragm and is prevented from entering the first guide section 270 and sheath 200, so that the catheter is not wetted prior to use. This configuration may have the advantage of prolonging the shelf life of the device. The diaphragm may be flat or may include extension 141 (as illustrated in FIGS. 7A and 7B, respectively). Once filled, tape strip 50 or another suitable closure is placed over the aperture or outlet to retain the wetting liquid 160 within the second guide section 20 (FIG. 7B). In still another configuration, the throughbore 23 of the second guide section 20 is a narrow throughbore resembling throughbore 74 of first guide section 70, as shown in FIGS. 2B and 2D, and is capable of containing the necessary amount of wetting liquid for wetting the hydrophilic catheter. This embodiment may be preferred for ease of manufacturing. Still another alternative is to include wetting liquid in both the sheath/first guide section and in the second guide section, particularly if a larger volume of liquid is desired for wetting the catheter.

[0069] Thus assembled, an above-described catheterization device, including wetting liquid and sealing tape or other suitable closure sealing the aperture of the catheter introducer, is sterilized in accordance with standard practices for similar medical devices (e.g., conventional irradiation techniques). The device is then stored in a sterile disposable wrapper until needed. In certain embodiments, the catheter device is part of a kit that includes one or more antiseptic-soaked swabs. Optionally, the kit may also contain gloves, a specimen container and/or a urine measuring container. Preferably the urine measuring container is a bag with volumetric markings and a specimen sampling port. The container is either already affixed to the catheter and/or sheath closure, or is adapted for attaching to the urine outlet at the time of use. As mentioned above, the urine container and the catheter sheath are attached or attachable in such a way that the wetting liquid cannot mix with the urine, and such that the catheter cannot slip into the collection bag, as illustrated in FIG. 8.

[0070] When the pre-wetted catheter configuration of the device is employed, the procedure commences immediately by first cleansing the urethral area, the person performing the catheterization removes the closure from aperture 27 of second guide section 20 or 220. For instance, an adherent seal is removed by pulling on a non-adherent portion, tab 52 (shown in FIG. 1A and 7B). Outlet 98 of catheter end 96 is positioned for discharging into either a collection or measuring container or bag, a portable waste receptacle, a toilet, or a specimen container. The catheter outlet may be conveniently attached to a collection vessel with precise measuring marks, to permit more accurate measurement of urine output than is typically possible with conventional hydrophilic catheter assemblies. Alternatively, a disposable collection vessel, which may include volumetric indicia and a

specimen retrieval port is combined with the introducer/catheter/sheath unit, for convenience.

[0071] The user's hands, while preferably being clean, do not have to be strictly "sterile" or gloved for this procedure, as long as care is taken not to directly touch the area of the urethral opening or the catheter during the catheterization. It is also important that the user not disconnect the two guide sections, if the catheter introducer is separable, or to otherwise breach the seal provided by diaphragm annular ring 44 such that outside contaminants can be introduced into the sterile interior of catheter introducer 15, or wetting liquid can spill.

[0072] Referring to FIGS. 1A-B, 2A, C, 6, and 7A-B, grasping catheter introducer 15 on the outer surface 28, the body contacting collar 37 is disposed against the urethral opening such that aperture 27 of second guide section 20 or 220 is aligned axially with the urethral opening. The catheter 90 is grasped through the soft, flexible sheathing material 100 (e.g., near the sheath retaining collar 86 of first catheter guide 70 (FIGS. 4A, B and E)) and the tip end 92 of the catheter is manually advanced in the first guide section until the scored central portion 42 or 142 of diaphragm 40 or 140 has been punctured or pierced by the tip end 92 of catheter 90. As a result, a tight fitting central aperture 46 or 146 in diaphragm 40 or 140 is formed through which the tip end of the catheter protrudes into the second guide section. As previously described, diaphragm 40 or 140 preferably comprises a conformable extension 41 or 141 made of a thin elastomeric material, but it may be shaped differently, as long as it is capable of functioning similarly to initially keep the wetting liquid from contacting the hydrophilic catheter, is penetrable to form and maintain a snug fitting, fluid blocking aperture 46 or 146 around the moving catheter.

[0073] If the catheter is not initially provided in wetted condition, and the second guide section contains the wetting liquid (FIG. 7B), the foregoing procedure is modified by first piercing the diaphragm and retracting the catheter tip, and allowing the liquid to enter the first guide section and sheath, to contact the hydrophilic portion of the catheter. If the second guide section is compressible, squeezing the catheter introducer, or at least the second guide section, may be employed to help expel the liquid through the diaphragm's aperture into the first guide section and where it can flow into the sheath lumen. The device can be inverted and manipulated to ensure that the liquid contacts the entire portion of the catheter that is enclosed by the sheath and first guide section. Squeezing of the compressible catheter introducer, or the second guide section and thereby contorting a flexible diaphragm and applying fluid force on the diaphragm may also be helpful prior to, or together with piercing by the catheter tip, to open the diaphragm. After the catheter becomes thoroughly wetted (e.g., about 20-30 seconds), the procedure then continues with removing the pressure resistant seal or cover at the outlet of the catheter introducer, cleansing the urethral opening, reinserting the catheter in the diaphragm aperture, and proceeding with moving the catheter forward into the second guide section and the urethra. Preferably, little or none of the wetting liquid is carried forward or spilled through the diaphragm as the catheter emerges from the catheter introducer.

[0074] Upon moving the catheter tip through the first guide 70 and into the second guide section 20, the resulting